

REMARKS/ARGUMENTS

Claims 1-14 are pending in the application. Claims 3 and 7-14 were previously provisionally withdrawn as being directed to a non-elected invention. Claim 1 has been amended for clarification. No new matter is added by this amendment. Reconsideration of this application and entry of this amendment are respectfully requested.

35 U.S.C. §103 Rejections - Ellis and Bagaoisan

Claims 1, 2, 4 and 5 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Number 5,514,093 to Ellis *et al.*, hereinafter "Ellis" in view of U.S. Patent Number 6,152,909 to Bagaoisan *et al.*, hereinafter "Bagaoisan." Applicant contends that the rejection has failed to meet the burden of presenting a prima facie case of obviousness.

The Combination of Ellis and Bagaoisan is Improper

First, applicant avers that the combination of Ellis and Bagaoisan is improper because Ellis is non-analogous art to the field of applicant's invention. See MPEP 2141.01(a), which quotes *In re Oetiker*, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992) as follows.

In order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned.

Applicant's invention is related to the field of aspiration catheters, as stated in paragraph 0001 and as required in the preamble of claim 1. Applicant's invention is particularly concerned with problems related to so-called "rapid-exchange" or "single-operator" types of aspiration catheters, as explained in paragraph 0009. Conversely, Ellis is related to balloon dilatation catheters, specifically wherein the length of the balloon may be selectively varied. See column 1, lines 6-11. Ellis does not relate to aspiration catheters, or to "rapid-exchange" or "single-operator" catheters of any kind. Thus, a person of ordinary skill would not reasonably be expected to look to Ellis for a solution to the "rapid-exchange" aspiration catheter problem facing the applicant.

Second, applicant also contends that the combination of Bagaoisan and Ellis is improper because the references do not contain some implicit or explicit reason, suggestion or motivation for a person of ordinary skill to combine the references in the way proposed by the rejection. See MPEP 2143.01. The rejection argues that the combination of Bagaoisan and Ellis would have been obvious to one of ordinary skill at the time of the invention "in order to better seal the catheter, and enter the patient at an oblique angle." See Detailed Action, page 3, last paragraph. The ambiguous "better sealing" and "entering the patient at an oblique angle" are not catheter problems addressed by any of Bagaoisan or Ellis or the applicant's invention. Therefore, applicant avers that the outstanding rejection uses impermissible hindsight as the motivation to combine the references. In view of the above arguments, the combination of Bagaoisan and Ellis is improper.

Ellis and Bagaoisan, Either Alone or in Combination, Fail to Disclose All Elements of Claim 1

Claim 1, as amended, requires

an aspiration catheter comprising:

a long, continuous aspiration shaft having a fixed length and an aspiration lumen extending between a distal aspiration port disposed at a distal tip of said aspiration catheter and *a proximal aspiration port disposed at a proximal end of said aspiration shaft, said proximal aspiration port adapted to be joined to a source of negative pressure;*

a proximal tube having a first lumen extending therethrough, wherein said proximal tube is slidably disposed over said aspiration shaft; and

a distal tube having a second lumen extending therethrough, wherein *said distal tube is slidably disposed over said aspiration shaft distal to said proximal tube, said distal tube is slidably positionable within said first lumen, at least a proximal end of said distal tube is unremovably disposed within said first lumen,* and said aspiration shaft is unremovable from said second lumen. Emphasis supplied.

First, Ellis' adapter 61 is not slidable with respect to inner member 12 to meet the claim requirement "said distal tube is slidably disposed over said aspiration shaft." Adapter 61 provides a connection between balloon proximal waist 28 and seal tube 62, which is a base for entire seal assembly 60. The distal waist of balloon 24 is secured to inner member 12 at its distal end 32. See column 7, lines 42-46. The movement of inner member 12 is transferred through balloon 24 and proximal waist 28 and adapter 61 to seal tube 62. Thus, the entire seal assembly 60 moves equally with inner member 12. See column 12, lines 16-29. Because Ellis' adapter 61 is not slidable with respect to inner member 12, Ellis fails to teach "said distal tube is slidably disposed over said aspiration shaft," as required in claim 1.

Second, Ellis' adapter 61 is secured via adhesive 64 to seal tube 62, and inflatable sealing membrane (81) 82 is also secured to seal tube 62. Therefore, adapter 61 is fixed with respect to membrane (81) 82. Since the "first lumen" is claimed as part of the claimed "proximal tube," then it is not reasonable to consider elements 61 and 82 of Ellis to teach "said distal tube is slidably positionable within said first lumen," as required by claim 1.

Third, because Ellis' adapter 61 and membrane (81) 82 are both secured to seal tube 62 at spaced-apart locations, adapter 61 cannot be disposed within membrane (81) 82. Therefore, it is not reasonable to consider elements 61 and 82 of Ellis to teach "at least a proximal end of said distal tube is unremovably disposed within said first lumen," as required by claim 1.

In summary, applicant contends that claim 1 is patentable because the rejection has failed to meet the burden of presenting a prima facie case of obviousness. The combination of Ellis and Bagaoisan is improper because Ellis is non-analogous art to the field of applicant's invention. In addition, at least three elements of claim 1 are not disclosed by Bagaoisan and Ellis, either alone or in combination. Applicant respectfully requests that the rejection of claim 1 be withdrawn.

Patentability of Claims 2, 4 and 5

Claim 2 depends from claim 1 and is patentable for the same reasons that claim 1 is patentable, as explained above. Claim 2 requires that "said distal aspiration port is set at an oblique angle." Ellis fails to disclose the limitations of claim 2, as admitted in the rejection at page 3, lines 3-6. To combine Bagaoisan with Ellis to meet the requirements of claim 2 is improper for the same reasons explained above.

Claim 4 depends from claim 1 and is patentable for the same reasons that claim 1 is patentable, as explained above. Furthermore, claim 4 further comprises "a guidewire shaft having a guidewire lumen disposed adjacent to said aspiration shaft." As described above, the rejection considers Ellis' inner tubular member 12 to correspond to the claimed aspiration shaft. Ellis describes element 12 as follows.

The inner tubular member 12 extends over the full length of the catheter assembly 10 and includes a guide wire lumen 13 extending axially therethrough. In use, the catheter assembly 10 is received over a guide wire 14 with the guide wire slidably received through the guide wire lumen 13. See column 7, lines 23-28.

Considering that Ellis' inner member 12 already contains guide wire lumen 13, it is improper to combine Bagaoisan for the purpose of providing a guidewire lumen, as proposed in the Detailed Action at page 3, paragraph 2. Indeed, Ellis teaches away from adding a (second) guidewire lumen because Ellis already has a guidewire lumen. See MPEP 2145 X(D). A prior art reference may be considered to teach away when

a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant. *In re Gurley*, 27 F.3d 551, 553, 31 USPQ2d 1130, 1131 (Fed. Cir. 1994).

Therefore, to combine Bagaoisan with Ellis to meet the requirements of claim 4 is improper for the reasons explained immediately above, and also explained further above regarding claim 1.

Claim 5 depends from claim 4 and is patentable for the reasons explained above regarding claim 4.

35 U.S.C. §103 Rejection - Ellis and Berthiaume

Claim 6 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Ellis in view of U.S. Patent Number 5,846,259 to Berthiaume. Claim 6 depends from claim 1 and is

patentable for the same reasons explained above with respect to claim 1. Furthermore, claim 6 requires six different stops, namely:

- a first proximal stop fixedly attached to an interior surface of said proximal tube on a proximal end thereof;

- a first distal stop fixedly attached to the interior surface of said proximal tube on a distal end thereof;

- a second proximal stop fixedly attached to an exterior surface of said distal tube on a proximal end thereof;

- a third proximal stop fixedly attached to an interior surface of said distal tube on a proximal end thereof;

- a second distal stop fixedly attached to the interior surface of said distal tube on a distal end thereof; and

- a fourth proximal stop fixedly attached to an exterior surface of said aspiration shaft in a distal region thereof.

Ellis and Berthiaume, Either Alone or in Combination, Fail to Disclose All Elements of Claim 6

First, in the rejection, at page 2, last paragraph, Ellis' stop 86 is considered to correspond to the "first distal stop fixedly attached to the interior surface of said proximal tube on a distal end thereof" as required by claim 6. As explained above, the rejection considers Ellis' inflatable sealing membrane (81) 82 to correspond to the claimed proximal tube. Ellis' stop 86 is, in fact, mounted to the inside surface of outer tubular member 16. See column 12, lines 40-41. Thus, the rejection mischaracterizes Ellis' stop 86 as being attached to the interior surface of membrane (81) 82.

Second, the rejection further mischaracterizes Ellis' adhesive means 64 as corresponding to the "third proximal stop fixedly attached to an interior surface of said distal tube on a proximal end thereof," of claim 6. However, Ellis' adhesive means 64 is no sliding stop, or travel stop, or stop of any kind. It is merely an adhesive to secure adapter 61 to sealing tube 62. See column 12, lines 24-25. In fact, rather than teaching a stop, adhesive means 64 is further evidence that adapter 61 cannot slide with respect to sealing tube 62 or membrane (81) 82. For this reason, in addition to the arguments above regarding claim 1, adapter 61 cannot reasonably be considered to correspond to the claimed distal tube.

Third, in the rejection, at page 4, third sentence, Berthiaume is combined with Ellis to provide, *inter alia*, a "first proximal stop fixedly attached to an interior surface of said proximal tube on a proximal end thereof," as required by claim 6. The rejection mischaracterizes Berthiaume as disclosing a "stop (43)" to meet this limitation. However, nowhere does Berthiaume disclose any element number 43, nor does Berthiaume disclose any stop attached to an interior surface of any tube on a proximal end thereof.

In summary, applicant contends that claim 6 is patentable because the rejection has failed to meet the burden of presenting a prima facie case of obviousness. Claim 6 is patentable for the same reasons that parent claim 1 is patentable, as explained above. In addition, at least three elements of claim 6 are not disclosed by Berthiaume and Ellis, either alone or in combination. Applicant respectfully requests that the rejection of claim 6 be withdrawn.

In consideration of the above arguments, Applicant respectfully requests that all the rejections under 35 U.S.C. §103(a) be withdrawn.

Conclusion

For the foregoing reasons, Applicant believes all pending claims not withdrawn are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (978) 739-3075 (Eastern Time).

Respectfully submitted,

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